

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON**

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION THIS DOCUMENT RELATES TO WAVE 1 CASES	Master File No. 2:12-MD-02327 JOSEPH R. GOODWIN U.S. DISTRICT JUDGE
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**PLAINTIFFS' MOTION TO DEFINE THE PERMISSIBLE SCOPE OF WAVE 1
DEFENSE MEDICAL EXAMS**

Before the Court are numerous Motions to Compel a Defense Medical Examinations (DME) of certain Plaintiffs in the Wave I discovery pool. Those facts underlying those motions differ in several key respects. For example, some of the requests are made in cases where Plaintiff has submitted to an IME by her own expert; others are requested in cases where the Plaintiff has not submitted to an IME by her own expert. Some request Plaintiff submit to a DME close to her home; others request that Plaintiff submit to a DME that requires significant travel. Some request that Plaintiff submit to a pelvic exam only; some request urodynamic testing and other invasive testing.

While there are issues that are unique to case attorneys (namely whether to allow Ethicon to conduct DME examinations of Plaintiff out of time), there are issues that predominate over all cases. Those issues – such as the scope of the DME, the permissible limits on the DME, the requirement for reimbursement of travel expenses and the like – should be determined on a global

basis. To that end, Counsel for the MDL plaintiffs (Tom Cartmell, Renee Baggett and Fidelma Fitzpatrick) engaged in a meet and confer with Ethicon on Wednesday, February 10, 2016.

During that call, Plaintiff agreed to work on the parameters of the DME. While not a waiver of the Plaintiffs' position that DME exams should not be compelled in this litigation, the Plaintiffs' counsel was mindful of the Court's previous rulings on that issue. Accordingly, Plaintiffs' counsel attempted to set forth some limitation and understandings on how the exams themselves would be conducted, as follows:

1. Individual case counsel should be consulted individually concerning the scheduling of the DME exam in their individual cases. However, as a general rule, the DME exam has to comply with the expert deadlines set forth in the Court's order governing the Wave 1 process.
2. Ethicon has not been provided the detail necessary under FRCP 35 when requesting the DME from Plaintiffs' counsel.
3. Ethicon must be responsible for payment for all costs reasonably incurred in association with the DME. This would include travel costs for companions if the Plaintiff is not able to travel independently. To facilitate the process, Plaintiffs will provide Ethicon with the information necessary to make the flight and hotel arrangements and Ethicon itself can book and pay for those arrangements. Each Plaintiff will submit incidental expenses to Ethicon after the DME.
4. Plaintiffs cannot be required to take time out of work (if applicable) for the DME. Instead, exams must be scheduled around the availability of the Plaintiff, including weekends.

5. Plaintiffs cannot be compelled to be seen by a male physician for a pelvic exam.
6. Plaintiffs cannot be compelled to travel out of town for a DME (though if they are able and willing to do so, Plaintiff will oblige).
7. Plaintiffs must be provided with the name of the expert and with their qualifications for performing a pelvic exam and be given the opportunity to object if they believe that the expert is not qualified in some way.
8. Plaintiffs decline to allow invasive urodynamic testing or a cystoscopy (which is an operative procedure).
9. As to ultrasound testing, Plaintiffs can only consent to a routine bladder ultrasound by a qualified urogynecologist. To the extent that Ethicon is looking for additional ultrasound testing, Plaintiffs will require a meet and confer to establish the necessity for the testing, its relationship to the injuries, and the qualifications of the expert administering the test.
10. The examination itself must be recorded by audio means.

During that call, counsel for the Plaintiffs' counsel also attempted to gain a better understanding of the process. They were told: (1) Ethicon had reached out to individual plaintiffs' counsel and requested that each enter into a stipulation concerning the scope and timing of DME exams; (2) while several plaintiffs' firms had agreed to such stipulations, they were not uniform in their scope; (3) that while Ethicon purported to want to reach a "global" resolution of the common issues, it was not willing to discontinue the competing stipulations it was seeking from individual case counsel. Most troubling to Plaintiffs MDL counsel was the last point – Ethicon, having delayed in seeking resolution of the DME issues since the entry of the Wave 1 order, was unwilling to work through this serious issue in a meaningful way, instead choosing to reach

piecemeal resolution in an inconsistent way across the board. This tactic was confirmed when Plaintiffs' counsel found out (from other case counsel) that Ethicon had unilaterally started to notice motions in various cases without providing any uniformity or allowing the process to be resolved globally.

The Plaintiffs' MDL counsel now respectfully requests that this Court order the following for all DMEs requested by Ethicon in Wave 1:

1. Ethicon is required to provide a complete disclosure pursuant to FRCP 35 in all cases where it seeks a DME no later than February 17, 2016. Failure to provide a disclosure pursuant to FRCP 35 precludes Ethicon from requesting and DME in an individual case.

Unlike other Defendants, Ethicon has not agreed to limit its requests for DMEs to those Plaintiffs who provided their own IME exam through an expert disclosure. Instead, according to Ethicon's counsel, it was seeking DMEs in some cases where no IME had been done by the Plaintiff. Similarly, Ethicon was not seeking DMEs in some Wave 1 cases where an IME has been done by the Plaintiff. Because of this, it is difficult for the case counsel and Plaintiff's MDL counsel to know at this point which Plaintiffs Ethicon expects to subject to an DME and which Plaintiffs Ethicon is waiving any request to an DME. To alleviate any confusion, Plaintiffs' counsel requests that Ethicon be required to identify all cases in which it seeks a DME no later than February 17, 2016.

Furthermore, Plaintiffs' counsel asks this court to prohibit a DME in any case where the Plaintiff has not submitted to an IME for her expert reports (and does not intend to do so). In those cases, no good cause is shown under FRCP 35 as to why Ethicon should be permitted to perform an invasive pelvic exam to further its defense of the case. The intensely private nature of the exams themselves militates against it – women should not be required to submit to a pelvic and vaginal exam as a prerequisite to bringing a pelvic mesh suit, particularly where the Plaintiff has not been

willing to submit to one for her own experts. It is difficult to believe that the Rules of Evidence could possibly allow Ethicon, or any other mesh manufacturer, to use the threat of a pelvic exam to dissuade Plaintiffs from pursuing their tort claims. This is particularly true in this class of women – women whose most intimate of areas have already been violated and injured by Ethicon’s pelvic mesh product. If a woman has chosen not to place her condition at issue through an IME of her own, she surely cannot be compelled to allow a pelvic exam against her will.

Finally, for those Plaintiffs who have submitted to (or are planning on submitting to) her own IME, Ethicon is required under FRCP 35 to disclose the “time, place, manner, conditions, and scope of the examination, as well as the person or persons who will perform it.” FRCP 35(a)(2)(B). *See Gurshin v. Bank of Am.*, 2016 U.S. Dist. LEXIS 10163 (D. Nev. Jan. 26, 2016) (“While Defendant is entitled to a Rule 35 examination of the Plaintiff, [the] court retains considerable discretion to establish manner, conditions and scope of the examination.” For example, the court is not bound by Defendant’s selection of a particular examining physician or psychologist.”). Ethicon did not provide this information to the Plaintiffs at the time it requested the DMEs; instead, this information has been trickling in as case counsel have requested it (though sometimes many days later).

Accordingly, Plaintiffs’ counsel requests that Ethicon be required to provide a complete disclosure pursuant to FRCP 35 in all cases where it seeks a DME no later than February 17, 2016. Failure to provide a disclosure pursuant to FRCP 35 precludes Ethicon from requesting and DME in an individual case.

2. Payment of Expenses

While Ethicon has agreed to “reimburse Plaintiff for reasonable expenses associated with the IME,” there is disagreement among the parties on how that should be done and the scope of the expenses.

First, for many of these Plaintiffs, they are unable to travel independently due to physical limitations and require a travel companion. Plaintiffs’ counsel request that the costs associated with this travelling companion must be borne by Ethicon.

Second, Plaintiffs believe that the logistics of arranging and paying for the travel to the examination should be borne by Ethicon. To that end, Plaintiffs’ counsel has proposed that individual Plaintiffs will provide Ethicon with the information necessary to make the flight and hotel arrangements and Ethicon itself can book and pay for those arrangements. Each Plaintiff will submit incidental expenses to Ethicon after the DME. This prevents any disputes concerning the “reasonableness” of the expenditures and short circuits the accounting and billing difficulties that can arise from this situation.

3. Plaintiffs cannot be required to take time out of work (if applicable) for the DME.

Some Plaintiffs are employed full time and cannot be required to take time out of work to submit to a DME. In several cases, Ethicon has requested that the Plaintiff travel long distances and submit to a DME during working hours – a request that can leave a Plaintiff without an income and taking time off of work for at least two days. Plaintiffs’ counsel requests that the DME, to the extent that it is ordered by this Court, take place during non-working hours (including weekends). In the alternative, Plaintiffs ask that Ethicon be ordered to reimburse Plaintiffs for lost wages if it cannot accommodate the Plaintiff’s work schedule.

4. Plaintiffs cannot be compelled to be seen by a male physician for a pelvic exam.

Given the intensely personal nature of the examination, Plaintiffs cannot be compelled to see a male physician for a pelvic exam. Ethicon has refused to agree to this for all Plaintiffs, instead arguing that the request is “not a problem unless your expert who did IME was a male.” Exh. 1. However, women simply cannot be compelled to undergo a pelvic exam by ANY man, regardless of whether she has submitted to pelvic exams by male physicians in the past. Each Plaintiff clearly understands that the DME is not conducted by her ally or advocate – in fact, they are conducted by physicians who are, by the nature of their relationship to the Defendant here, adversaries in this litigation process. Women cannot be ordered to submit to pelvic examinations by men who are their adversaries in litigation and must be afforded the ability to request an exam by a female physician.

5. Plaintiffs cannot be compelled to travel out of town for a DME (though if they are willing to do so, we would make them available to travel).

Many of the requests for DMEs require out of town travel. For some Plaintiffs, that may not pose a problem. For others, it is a significant issue in many ways: some are physically unable to travel; some have personal obligations that make it extremely difficult, if not impossible, to travel; some may never have travelled much in their lives and are not familiar with the travel systems; some simply don't have the luxury of time to travel to and from the DME. It is a hardship – and not reasonable – to require women who are not able to travel to submit to an examination that is out of town. That transforms a 1-2 hour physician appointment potentially into a 2 day travel experience and is unreasonable.

6. Plaintiffs should not be required to undergo invasive urodynamic testing or a cystoscopy

Some requests for a DME have included requests for cystoscopies and urodynamic studies. Cystoscopy and Urodynamic testing are procedures with associated risks and requiring consent

from the patient. Specifically, according to the U.S. Department of Health and Human Services, (<http://www.niddk.nih.gov/health-information/health-topics/diagnostic-tests/cystoscopy-ureteroscopy/Pages/default.aspx#risks>), cystoscopies carry the following risks:

- UTIs
- abnormal bleeding
- abdominal pain
- a burning feeling or pain during urination
- injury to the urethra, bladder, or ureters
- urethral narrowing due to scar tissue formation
- the inability to urinate due to swelling of surrounding tissues
- complications from anesthesia

Likewise, urodynamic testing can cause “mild discomfort for a few hours when urinating . . . The health care provider may recommend taking a warm bath or holding a warm, damp washcloth over the urethral opening to relieve the discomfort. An antibiotic may be prescribed for 1 or 2 days to prevent infection, but not always. People with signs of infection—including pain, chills, or fever—should call their health care provider immediately.” <http://www.niddk.nih.gov/health-information/health-topics/diagnostic-tests/urodynamic-testing/Pages/20Testing.aspx>. Each of these procedures required informed consent.

Women cannot be compelled to waive their informed consent and to submit to an invasive procedure that has potential risks to them. As the American College of Obstetricians and Gynecologists has stated, “[a]s an ethical doctrine, informed consent is a process of communication whereby a patient is enabled to make an informed and voluntary decision about accepting or declining medical care.” Exh. 2. Here, women cannot be forced to forfeit their right to make a decision about accepting or declining medical treatment – thereby subjecting themselves to additional risks and potential complications -- simply because they filed a lawsuit.

7. Plaintiffs Cannot Be Compelled to Submit to Ultrasounds (Other Than Routine Bladder Ultrasounds) Absent a Meet and Confer Process

This Court has already ordered that Plaintiffs submit to a routine bladder ultrasound if necessary as part of a DME. Without waiving the objections to that order, Plaintiffs' counsel seek to limit a different type of ultrasound: Pelvic floor ultrasonography. Ultrasonography for visualization of the pelvic floor and mesh devices differs from traditional abdominal or even endovaginal ultrasound. The methodology is well-reported, but requires highly specialized equipment and expertise for the performance and interpretation of the findings. To achieve a complete anatomical evaluation of this region, the different ultrasound techniques (transvaginal sonography (TVS), endoanal ultrasound (EAUS) and transperineal ultrasound (TPUS)) for pelvic floor imaging are usually combined. "Their standardization (with respect to equipment, patient preparation and position, examination technique, image orientation, imaging planes and manner of performing measurements) is essential for repeatability." Santoro *et al.*, "State of the art: an integrated approach to pelvic floor ultrasonography," *Ultrasound Obstet Gynecol* 2011; 37: 381-396. This testing can cause significant discomfort, particularly in the presence of mesh and associated inflammation and scarring. Physicians performing these ultrasounds should have demonstrated competence and certification.

Because of the specialized and highly invasive nature of this testing, Plaintiffs have requested that any request for pelvic floor ultrasonography be accompanied by a meet and confer on the qualifications of the expert to conduct such testing, the nature of the testing to be performed, and the necessity for the testing.

8. The examination itself must be recorded by audio means

Although this Court has previously declined to allow the DME to be recorded by audio or visual means, Plaintiffs' counsel believes that this ruling should be revisited in light of the trial experience in these cases.

As has been previously addressed, these examinations are not conducted by an independent, neutral party. Instead, they are conducted by the Defendants' consultants in this litigation. To allow these examinations to go forward without a witness and without an audio recording is to allow Ethicon 90 plus minutes with our clients outside her attorney's presence. Furthermore, during trials in pelvic mesh matters across the country, the testimony of the Defense consultant and Plaintiff has sometimes differed on who said what to whom, when it was said, and the import of the conversation. A jury has then been faced with the job of assessing whose version of events is accurate – an issue that quickly disappears with a transcription of the actual exam itself. That transcription can be used to establish what Plaintiff told the doctor, what the doctor told the Plaintiff, and does absolutely nothing to compromise the findings upon exam. There is simply no reason to deny a Plaintiff a witness, a recording, and force her to subject herself to an exam by a litigation opponent, particularly when there is absolutely no prejudice to the Defendants from allowing the recording and transcription to go forward.

This 16th Day of February, 2016

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CERTIFICATE OF SERVICE

I hereby certify that I filed the foregoing document on February 16, 2016, using the Court's CM-ECF filing system, thereby sending notice of the filing to all counsel of record in this matter.

/s/ Fidelma L. Fitzpatrick
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